

SUPPLEMENTARY GAZETTE



THE SOUTH AUSTRALIAN GOVERNMENT GAZETTE

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STATE GOVERNMENT INSTRUMENTS

CONTROLLED SUBSTANCES (POISONS) REGULATIONS 2011

Community Pharmacy Oral Contraceptive Pill Resupply Services Scheme under Regulation 21(2)(h)

I, CHRIS PICTON, Minister for Health and Wellbeing, hereby determine the Community Pharmacy Oral Contraceptive Pill Resupply Services Scheme (**Scheme**) set out in this notice to be a scheme for the purposes of Regulation 21(2)(h) of the *Controlled Substances (Poisons) Regulations 2011*:

Medicines that may be sold or supplied without a prescription by a pharmacist under the Scheme:

1. The following Schedule 4 oral contraceptive pills (**OCPs**) are the only OCPs which may be sold or supplied by a pharmacist to a person without a prescription. Combined OCPs or progestogen only pills containing:
 - a. Permitted estrogens:
 - i. Ethinylestradiol (40 micrograms or less)
 - ii. Estradiol
 - b. Permitted progestogens
 - i. Levonorgestrel
 - ii. Norethisterone
 - iii. Drospirenone
 - iv. Nomegestrol
 - v. Desogestrel
 - vi. Dienogest
 - vii. Gestodene
 - viii. Cyproterone

Combined OCPs with a high estrogen dose (50 micrograms of ethinylestradiol or equivalent) are not permitted to be sold or supplied by a pharmacist under the Scheme.

Combined OCPs containing estetrol or mestranol are not permitted to be sold or supplied by a pharmacist under the Scheme.

All instruments appearing in this gazette are to be considered official, and obeyed as such

Requirements with respect to the Sale or Supply of the Schedule 4 medicines to which this Scheme applies:

2. A pharmacist is not permitted to initiate or change a person's OCP therapy.
3. A pharmacist must not sell or supply the OCP in a quantity that exceeds one original manufacturer's pack of the OCP.
4. The OCP is only sold or supplied by a pharmacist to eligible persons (see paragraph 6 below) and in accordance with the SA Community Pharmacy Oral Contraceptive Pill Resupply Services Management Protocol (**OCP Resupply Management Protocol**) and relevant professional practice standards and guidelines, including the professional practice standards and guidelines referred to in the OCP Resupply Management Protocol.
5. The supply, packaging and labelling of the approved OCPs must be in accordance with the requirements in the *Controlled Substances Act (1984)* and the *Controlled Substances (Poisons) Regulations 2011*.

Person's eligibility under the Scheme:

6. The only persons who are eligible to be sold or supplied OCPs by a pharmacist under the Scheme are persons who:
 - a. have been supplied or prescribed the OCP by a registered medical practitioner or other registered health practitioner (acting in the ordinary course of their profession) for the previous 2 years; and
 - b. have a history of stable continuous use of the OCP for the previous 2 years; and
 - c. have been reviewed by a registered medical practitioner or other appropriate registered health practitioner (acting in the ordinary course of their profession) within the last 2 years with respect to their use of the OCP; and
 - d. meet the inclusion criteria in accordance with the OCP Resupply Management Protocol and relevant professional practice standards and guidelines, including the professional practice standards and guidelines referred to in the OCP Resupply Management Protocol.

Quantity of OCP which may be Resupplied by a Pharmacist under the Scheme:

7. A pharmacist may only sell or supply:
 - a. one original manufacturer's pack of an approved OCP at any one time; and
 - b. additional original manufacturer's packs of an approved OCP, up to a maximum of 12 months' supply of the OCP in total;to a person aged 17 to 40 years (who is eligible to be sold or supplied OCPs by a pharmacist under the Scheme).
8. A pharmacist may only sell or supply one original manufacturer's pack of an approved OCP to a person aged between 41 and 50 years (who is eligible to be sold or supplied OCPs by a pharmacist under the Scheme). Following this sale or supply the person must consult a registered medical practitioner or other registered health practitioner (acting in the ordinary course of their profession) and obtain a new prescription for an OCP.

Pharmacist Requirements under the Scheme:

9. Pharmacists who sell or supply an OCP to a person must have an unconditional general registration with the Australian Health Practitioner Regulation Agency (**Ahprra**).
10. Pharmacists must comply with all relevant legislation, Ahpra & the Pharmacy Board of Australia's Code of Conduct, and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.
11. Prior to providing services, pharmacists must have successfully completed the approved training set out in paragraph 12 of the Scheme, and must maintain eligibility to provide services, including any ongoing training and professional development.

Pharmacist training requirements under the Scheme:

12. Prior to providing services, pharmacists must have successfully completed one or more of the competency-based training programs on contraception specified in the SA Community Pharmacy OCP Resupply Services Management Protocol, delivered through a higher education institution accredited by the Tertiary Education Quality and Standards Agency or an accredited continuing professional development program, that meets the Australian Pharmacy Council's Standards for Continuing Professional Development Activities.
13. Pharmacists must complete cultural safety and gender diversity training relevant to their place of practice, reflect on their competency and provide the service in ways that are inclusive, culturally safe, sensitive, and responsive.

Pharmacy requirements under the Scheme:

14. Only pharmacies registered by the Pharmacy Regulation Authority of South Australia (PRASA) under the *Health Practitioner Regulation National Law (South Australia) Act 2010* may participate in the Scheme.
15. The pharmacy must have an area suitable to maintain confidentiality of the consultation with the person, i.e. have a screened or private consulting area that:
 - a. ensures a person's privacy and confidentiality, including visual and auditory privacy
 - b. has sufficient space to allow the presence of the person, a carer if required, the pharmacist, and relevant equipment and documentation.

Clinical documentation and communication requirements under the Scheme:

16. Pharmacists must make a clinical record and a record in a pharmacy dispensing system regarding the sale or supply of any OCP under the Scheme.
17. The pharmacist is required, to make and keep (at the pharmacy where the consultation with the person occurred) a comprehensive clinical record of the consultation and of any treatment provided, in accordance with relevant legislation and professional responsibilities. The record must include:
 - a. sufficient information to identify the person
 - b. the name of the pharmacist who undertook the consultation and their healthcare identifier number (HPI-I)
 - c. the date of the consultation
 - d. information relevant to the person's treatment (for example, the person's medical history, adverse drug reactions)
 - e. any clinical opinion reached, and actions taken by the pharmacist
 - f. details of the OCP sold or supplied to the person (generic name, form, strength and quantity)
 - g. any information or advice given by the pharmacist to the person in relation to any proposed treatment

- h. details of any referrals made to a medical practitioner or other healthcare practitioner
 - i. any consent given by a person to the consultation, supply of medication, treatment proposed, and sharing of information with their medical practitioner or other relevant healthcare practitioners or services.
18. Where a person has a My Health Record, the pharmacist must ensure the details of the OCP sold or supplied are uploaded to My Health Record, unless otherwise requested by the person.
 19. The pharmacist must offer a record of the service to the person. This may include a copy of the checklist completed by the pharmacist during the consultation. The patient may choose to share this with their medical practitioner or other healthcare practitioners or services.
 20. The pharmacist may share a record of the supply and consultation with the person's usual treating registered medical practitioner or medical practice, or other relevant healthcare practitioners or services, with the consent by the person.
 21. Pharmacists will ensure continuity of care and use their professional discretion to refer the patient to health professionals or services where appropriate, and where eligibility criteria are not met. This includes immediate referral with relevant patient information when required.
 22. Pharmacists must, at the request of the Minister for Health and Wellbeing, provide data on the scheme periodically (for monitoring and evaluation purposes).

Consultation fees

23. Pharmacists may charge a consultation fee for the service, in addition to the cost of any OCP that is supplied.
24. Pharmacists should ensure that the person understands the costs involved when offering the service.

Commencement of Scheme

25. This Scheme commences on 6 May 2024

The SA Community Pharmacy Oral Contraceptive Pill (OCP) Resupply Services Management Protocol means the document of that name published by the Department (as amended from time to time).

Dated: 8 April 2024

HON CHRIS PICTON MP
Minister for Health and Wellbeing
